

Notice of Allowability

Application No.

09/993,777

Examiner

Zachariah Lucas

Applicant(s)

WILD ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response of January 20, 2004.
2. ☒ The allowed claim(s) is/are 39-49.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 1/20/2004
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 4-14 and 4-15 2004.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of the Claims

1. Claims 39-49 are pending in the application. Claims 39-43, and 45-49 are under consideration, and claim 43 was withdrawn as to a non-elected invention. The claims under consideration were rejected in the prior action, mailed on July 15, 2003. In the Response filed on January 15, 2004, the Applicant amended claims 39, 40, 42, and 44-46.
2. Claims 39-42, and 44-49 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 43, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, is now subject to being rejoined. Claim 43 is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in the telephone interviews with Michael Davis on April 14, 2004 and April 15, 2004.

The application has been amended as follows:

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Claim 40 has been amended as follows:

in line 2 of the claim, the phrase "isolated nucleic acid molecule is genomic DNA" has been deleted, and the phrase - -polypeptide is encoded by a nucleotide sequence- - has been inserted in its place.

Claim 43 has been amended as follows:

in line 1 of the claim, the phrase - - an infection due to infectious laryngotracheitis virus- - was inserted between the words "diagnosing" and "which";

in line 7 of the claim, a comma and the word - - and- - were inserted between the words "subject" and "thereby", such that the claim now reads, in relevant part, "in the subject, and thereby..."; and

in line 7 of the claim, the phrase - -infection due to- - was inserted between the words "diagnosing" and "infectious."

Claim 45 has been amended as follows:

in line 2 of the claim, the phrase "genomic DNA encoding" has been deleted, and the phrase - - a nucleotide sequence encoding- - has been inserted in its place; and

in line 3 of the claim, the phrase "genomic DNA" has been deleted, and the phrase - - nucleotide sequence- - has been inserted in its place.

These changes to claim 43 were made to clarify what was being diagnosed by the claimed method, and to correct the language of the claim. The amendments of claims 40 and 45 were not

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deemed to affect the patentability of the claims.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on January 20, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

5. **(Prior Objection-Withdrawn)** The disclosure was objected to because of the following informalities: On page 29 of the application, the description states that the "invention provides an isolated nucleic acid molecule encoding" one of a series of genes. However, nucleic acids do not encode genes. On the same page (lines 5-17), the application indicates that the sequences of SEQ ID NOs: 60-70 are gene sequences. However, these sequences are actually the protein sequences encoded by the genes.

In view of the amendments to the specification, the objections are withdrawn.

Double Patenting

6. **(Prior Rejections- Withdrawn)** Claims 39-41, and 44- 46 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 20, 24, and 28 of U.S. Patent No. 6,328,975; over claims 14, 30, 33, and 35 of U.S. Patent No. 6,497,882; over claims 21, 37, and 40-42 of U.S. Patent No. 6,221,361; and claims 23, 28, and 32 of U.S. Patent No. 6,033,904. In view of the amendment of the claims of the

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present invention limiting them to embodiments wherein the nucleic acid encodes the ILTV gI protein of SEQ ID NO: 7, the rejections are withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 39-41, and 44-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48 and 50 of copending Application No. 09/994,064. This rejection was withdrawn in the interview of September 15, 2003 as indicated in the interview summary mailed on September 25, 2003.

Claim Rejections - 35 USC § 112

8. **(Prior Rejection- Withdrawn)** Claims 39-42, and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected because the Applicant lacked sufficient written description support for the claimed genera of nucleic acids encoding for any ILTV glycoprotein I, and for nucleic acids comprising genomic DNA encoding ILTV gI. In view of the amendments to the claims limiting them to nucleic acids encoding the ILTV gI protein of SEQ ID NO: 7, or to nucleic acids comprising the genomic DNA of SEQ ID NO: 1, the rejection is withdrawn.

Claims 47 and 49 were further rejected for reading on nucleic acids that encode for not only ILTV glycoprotein I, but also for ILTV glycoprotein D. This portion of the rejection was withdrawn as indicated in the interview summary mailed September 25, 2003.

9. **(Prior Rejection- Withdrawn)** Claim 41 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is withdrawn in view of Applicant's arguments, which are persuasive.

Claim Rejections - 35 USC § 102

10. **(Prior Rejections- Withdrawn)** Claims 39, 40, and 41 were rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard et al., WO 92/03554 (of record in the Feb. 15, 2002 IDS), and claims 39 and 40 were rejected under 35 U.S.C. 102(e) as being anticipated by Keeler et al., U.S. Patent 5,279,965. The claims have been amended such that they are limited to isolated DNA comprising nucleic acids encoding the ILTV gI of SEQ ID NO: 7. In view of the apparent heterogeneity of ILTV sequences (See e.g., Protein Accession Numbers AAB28457 and AAC55098, demonstrating sequence variation among ILTV proteins, and therefore the genes encoding them), and the fact that neither the Keeler or the Sheppard references disclose the sequence of the isolated ILTV, the references do not appear to either anticipate or render obvious the specific ILTV gI gene of the present claims. The rejections are therefore withdrawn.

11. **(Prior Rejection-Withdrawn)** Claims 39-41, 44, 45, 46, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Cochran et al., U.S. Patent 5,869,312. The rejected claims read on nucleic acid molecules, including recombinant molecules, that encode the gI protein of ILTV. In columns 20-21, the reference describes a plasmid comprising the coding region for ILTV gI, and a method of making it. In view of the Declaration presented by Dr. Cochran and the arguments in the Response, this rejection is withdrawn.

Allowable Subject Matter

12. Claims 39-49 are allowed.

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13. The following is an examiner's statement of reasons for allowance: as indicated above, the claims have been amended such that they read on isolated nucleic acids either encoding a specific ILTV gI protein sequence, or comprising a specific ILTV gI gene. In view of these amendments, the fact that the teachings in the art appear to demonstrate heterogeneity among ILTV viral sequences, and that the sequences indicated in the claims are not part of the prior art, the claims are allowed.

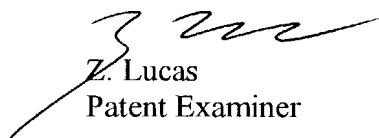
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
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